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| 10/541,633 | 06/30/2006 | Oliver Planz | 7003/42 | 3490 |

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| EXAMINER | |
|---|---|
| JAVANMARD, SAHAR | |

| ART UNIT | PAPER NUMBER |
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| 1617 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/541,633 | PLANZ ET AL. | |
| | Examiner | Art Unit | |
| | SAHAR JAVANMARD | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *5-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/31/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Claims*

This Office Action is in response to Applicant's Restriction Requirement remarks filed on February 4, 2008. Claim(s) 1-16 are pending. Claim(s) 5-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant's election of Group I drawn to a method of treatment of at least one viral disease and election of species of the active ingredient (acetyl salicylic acid) and a component of the NF-kB signal transduction pathway (comprising inhibitor of NF-kB kinase alpha (IKKalpha), inhibitor of NF-kB kinase beta (IKKbeta), and inhibitor of kB (IkB)) without traverse of the restriction requirement in the reply is acknowledged. The requirement is deemed proper and is therefore made FINAL. Claim(s) 1-4 and 16 are examined herein insofar as they read on the elected invention and species.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 16 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for a

method for the treatment of at least one viral disease comprising administering a physiologically effective dose of a pharmaceutical composition comprising at least one active ingredient which comprises acetyl salicylic acid which inhibits an NF-kB signal transduction pathway such that viral multiplication is inhibited, however, does not reasonably provide enablement for the prophylaxis of said method as recited in these claims.

The instant claims are drawn to a method for the prophylaxis (prevention) of treatment of at least one viral disease comprising administering a physiologically effective dose of a pharmaceutical composition comprising at least one active ingredient which comprises acetyl salicylic acid which inhibits an NF-kB signal transduction pathway such that viral multiplication is inhibited. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The instant invention pertains to a method for the prophylaxis (prevention) of treatment of at least one viral disease comprising administering a physiologically effective dose of a pharmaceutical composition comprising at least one active ingredient which comprises acetyl salicylic acid which inhibits an NF-kB signal transduction pathway such that viral multiplication is inhibited.

The state of the prior art:

The skilled artisan would view that the prophylaxis (prevention) of one or more symptoms of a viral disease totally, absolutely, or permanently, is highly unlikely, since one cannot guarantee that the viral disease will always be prevented.

The relative skill of those in the art:

The relative skill of those in the art is very high.

The predictability or lack thereof in the art:

The skilled artisan would view that the prevention of a viral disease, absolutely, or permanently is highly unpredictable.

The amount of direction or guidance presented and the presence or absence of working examples:

In the instant case, no working examples are presented in the specification as filed showing how to prevent a viral disease totally, absolutely, or permanently. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

*Genentech, Inc. v. Novo Nordisk*, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test the combination in the instant claims whether preventing a viral disease totally, absolutely, or permanently.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiscott (*J. Clin. Inv.*, 2001) in view of Kopp et al. (*Science*, 1994).

Hiscott teaches that NF-kB can be activated by multiple families of viruses, including HIV-1, HTLV-1, hepatitis B virus (HBV), hepatitis C virus (HPC), and influenza virus. Further, Hiscott teaches that this activation may serve several functions, including viral replication, prevent virus-induced apoptosis, and mediate the immune response to the invading pathogen (page 144, column 2, first full paragraph).

Hiscott does not teach the inhibition of NF-kB or the inhibition thereof with aspirin.

Kopp teaches that NF-kB activity is inhibited by sodium salicylate and aspirin (acteylsalicylic acid) (page 958, column 3, 1st full paragraph).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the teachings of Hiscott that influenza viruses, for example, are capable of activating NF-kB, thereby inducing viral replication and inhibited this activity with acetylsalicylic acid as taught by Kopp.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiscott (*J. Clin. Inv.*, 2001) in view of Kopp et al. (*Science*, 1994) as applied to claims 1-4 above in further view of Prince et al. (US Patent No. 5,290,540).

Hiscott and Kopp are discussed above.

Kopp does not teach aerogenic administration of acetylsalicylic acid.

Prince teaches a method in which an anti-inflammatory agent and acetylsalicylic acid are administered in the form of an aerosol (claim 1) at a dosage of from 0.1 μg to 1000 mg/kg body weight (claim 21).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have administered acetylsalicylic acid to inhibit the activation of NF-kB in order to treat viral replication as taught by Hiscott and Kopp above and administered the aspirin in an aerogenic form. The motivation taught by Prince is that aerogenic administration of acetylsalicylic acid is an effective and rapid method of treating lower respiratory tract disease caused particularly by parainfluenza virus type 3 (column 1, lines 10-17). Thus one of ordinary skill in

the art would expect with a reasonable degree of success that aerosolic administration of acetylsalicyclic acid could also be used to treat other influenza viruses.

***Conclusion***

Claims 1-4 and 16 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sahar Javanmard whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

SJ

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617